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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,825	09/16/2003	Yoshikazu Amano	Q77478	1097

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EXAMINER	
BOWERS, NATHAN ANDREW	
ART UNIT	**PAPER NUMBER**
1744	

DATE MAILED: 06/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/662,825	AMANO, YOSHIKAZU	
	Examiner	Art Unit	
	Nathan A. Bowers	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "quality material" in claim 17 is a relative term which renders the claim indefinite. The term "quality material" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. One of ordinary skill in the art would not understand the metes and bounds of the claim since "quality materials" are not clearly defined in the art. Furthermore, the specification does not adequately disclose the qualities and characteristics of "quality materials" in such a way that the invention can be reproduced and practiced.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1) Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Neriishi (US 20020197568).

With respect to claims 1, 3, and 5, Neriishi discloses a biochemical analysis unit comprising a base plate (Figure 1:5), which has a plurality of holes (Figure 2:6). This is disclosed in paragraphs [0030]-[0039] and [0100]. Paragraph [0206] states that the base plate is constructed from any material that has radiation attenuating properties and/or light attenuating properties. Paragraphs [0234]-[0237] disclose that a porous adsorptive material (Figure 36:221) is filled in each of the plurality of holes in order to form a plurality of adsorptive regions. It is further stated that the pores in the adsorptive material each have a diameter falling within the range of 0.1 to 50 μm. This anticipates pore diameter ranges of 1 μm to 10 μm, 1 μm to 5 μm, and 2 μm to 4 μm. Furthermore, Neriishi discloses that the use of fluorescence as a means by which to detect the presence of biochemical analytes. This is disclosed in paragraphs [0033], [0112]-[0135] and throughout the reference.

With respect to claims 2, 4, and 6, Neriishi discloses the apparatus in claim 1, wherein the porous adsorptive material takes on the form of a film. [0234]-[0237] and Figure 36 demonstrate how a porous adsorptive film is fitted into the holes formed in the base plate. Again, it is stated that the pores in the adsorptive film each have a diameter falling within the range of 0.1 to 50 μm. This anticipates pore diameter ranges of 1 μm to 10 μm, 1 μm to 5 μm, and 2 μm to 4 μm.

With respect to claims 7-11, Neriishi discloses the apparatus in claim 1 wherein the base plate reduces light passing through the wall to an intensity of at most 1/10 of the original intensity. Neriishi teaches that the base plate has a mean density of at least 0.6 g/cm^3 and in the

range of 1 g/cm^3 to 20 g/cm^3. It is further taught that the base plate has a thickness within the range of 50 microns to 1,000 microns. This is disclosed in paragraphs [0213] and [0214].

With respect to claims 14 and 15, Neriishi discloses the apparatus in claim 1 wherein the pitch of the holes is between 0.05 mm and 3 mm, and the spacing between two adjacent holes is between 0.01 mm and 1.5 mm. This is disclosed in paragraph [0215].

With respect to claim 17, Neriishi discloses the apparatus in claim 1 wherein the porous adsorptive material includes a porous quality material and a fiber material. In paragraph [0100], Neriishi discloses that the porous material is made from 6-nylon, which is disclosed by Applicant in paragraphs [0044] and [0045] to be both a porous quality material and a fiber material.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2) Claims 1, 3, and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagasawa (US 20020127585) in view of Maul (US 5955377), Beattie (US 5843767) and Fernwood (US 4493815).

With respect to claims 1, 3 and 5, Nagasawa discloses a biochemical analysis unit comprising a base plate (Figure 1:2), which has a plurality of holes (Figure 1:3). A porous adsorptive material (Figure 1:1) is filled in each of the plurality of holes in order to form a plurality of adsorptive regions. This is disclosed in paragraphs [0012]-[0019] and [0046].

Nagasawa teaches that different biological probe materials are adsorbed upon the porous materials that are placed into the holes. Furthermore, Nagasawa discloses that the use of fluorescence as a means by which to detect the presence of biochemical analytes. This is disclosed in paragraphs [0024]-[0030] and throughout the reference. Nagasawa, however, does not expressly disclose that the base plate is made of a material having radiation and/or light attenuating properties, or that the pore diameter is within the range of 1 μm to 10 μm.

Maul discloses a kit for detecting the presence of a biochemical analyte of interest. Maul teaches that probe arrays are immobilized upon a base plate in order to selectively bind to a desired molecule in a sample. Detection of binding events is accomplished by using a substrate which has an optically active surface that exhibits a response to impinging light. Column 12, lines 1-21 teach that the substrate is made from light attenuating materials.

Beattie discloses a biochemical analysis unit in which a plurality of nucleic acid probe arrays are immobilized within densely packed pores or channels that are arranged in patches across a base plate. This is disclosed in column 5, line 26 to column 7, line 15. Column 11, line 58 to column 12, line 21 states that the pores are characterized by diameters selected over the range from 2 nm to several micrometers.

Fernwood discloses a biochemical test plate in which a plate (Figure 1:2) is provided having a plurality of holes therethrough. A porous adsorptive material (Figure 1:3) is arranged underneath the holes. One of ordinary skill in the art would recognize that when the biochemical analysis unit is formed by the compression of the screws (Figure 1:19) that the porous material forming the bottom of the holes would be partially within the holes of the plate. Furthermore,

Fernwood states that the porous material comprises pores with 1 micron diameters. This is disclosed in column 2, line 65 to column 4, line 3.

Nagasawa, Maul, Beattie and Fernwood are analogous art because they are from the same endeavor regarding biochemical analysis units for the detection of a biological analyte.

At the time of the invention, it would have been obvious to alter Nagasawa's device in order to incorporate into the overall design a light attenuating base plate, as well as adsorptive materials with pore diameters of a few micrometers. Light attenuating materials are beneficial because they serve to improve signal to background behavior and enhance detection levels during optical analysis. Beattie teaches in column 4, lines 20-28 that it is well known in the art to use light attenuating materials to help determine the specific sites where hybridization has taken place. It also would have been beneficial to ensure that the pore diameter of the adsorptive material in Nagasawa's apparatus was within the range of 1 μm to 10 μm, and more specifically, 1 μm to 5 μm or 2 μm to 4 μm. In column 1, lines 43-45 and column 9, lines 46-59, Beattie teaches that small pore sizes help to increase the surface area available at the array. This allows for greater amounts of biochemical probes to be immobilized at the pores, which in turn helps to increase the efficiency of hybridization.

With respect to claims 7-11, Nagasawa, Maul, Beattie and Fernwood disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above. Although the combination does not expressly disclose to what extent the intensity of the light passing through the substrate wall is reduced, it would have been obvious to ensure that it was reduced to an intensity of at most 1/10 of its original intensity. Varying the light attenuating properties of the

plate in order to achieve the most favorable design is simply the optimization of result effective variables that could be pursued using routine experimentation in which the density and thickness of the plate is systematically altered and tested. In the absence of new or unexpected results, it would have been obvious to ensure that the base plate reduced the intensity of light by one-tenth if it was determined that this was necessary to produce and detect reliable results. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

With respect to claims 12 and 13, Nagasawa, Maul, Beattie and Fernwood disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above, wherein each of the plurality of holes has an area of opening between 0.001 mm^2 and 0.3 mm^2. In paragraph [0063], Nagasawa teaches that the holes have a diameter of 0.5 mm. Since the holes are depicted as circles in the Figures, it can be determined that the openings of the holes are within the claimed range.

With respect to claim 16, Nagasawa, Maul, Beattie and Fernwood disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above, wherein the array density of the plurality of holes falls within the range of at least 10 holes/cm^2 to 100,000 holes/cm^2. In paragraphs [0081] and [0083], Nagasawa discloses examples in which a glass substrate (50 X 30 mm and 80 X 30 mm) contains a plurality of holes having 2 and 0.5 mm diameters. From these examples, it can be reasonably determined that Nagasawa's invention is characterized by an array density similar to that claimed by Applicant.

With respect to claim 17, Nagasawa, Maul, Beattie and Fernwood disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above. In addition, Fernwood teaches in column 3, lines 49-62 that it is known in the art to utilize porous membranes made from quality materials and fiber materials during hybridization detection procedures. Fernwood discloses the use of nylon, which is classified as a quality material in paragraphs [0044] and [0045] of Applicant's specification. Fernwood also discloses a plurality of fibrous membrane materials.

At the time of the invention, it would have been obvious to ensure that the membrane materials used in Nagasawa's invention were the same as those described by Fernwood. Fernwood's quality and fiber membrane materials represent a viable and effective alternative to those disclosed by Nagasawa. Absent a showing of criticality, it would have been apparent to use these membrane materials if it was determined that they exhibited the best results.

With respect to claims 18-20, Nagasawa, Maul, Beattie and Fernwood disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above. Although the combination does not expressly disclose the invention's signal to noise ratio during detection, it would have been obvious to ensure that it was greater than or equal to 1,888,000. Varying the properties of the invention (namely the pore diameter) in order to increase the signal to noise ratio and achieve the most favorable design is simply the optimization of result effective variables that could be pursued using routine experimentation. In the absence of new or unexpected results, it would have been obvious to ensure that the signal to noise ratio has high if it was determined that this was necessary to produce and detect reliable results. Furthermore, it

is believed that Nagasawa, Maul, Beattie and Fernwood's invention is intrinsically capable of obtaining this ratio since Beattie and Fernwood disclose the use of porous membranes characterized by a low pore diameter. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Response to Arguments

Applicant's arguments, see pages 7 and 8, filed 6 April 2006, with respect to the 35 U.S.C. 102 rejections involving Hosoi have been fully considered and are persuasive. The rejections of claims 1, 3 and 5 have been withdrawn.

Applicant's arguments filed 11 April 2006 have been fully considered but they are not persuasive.

Applicant's principle arguments in regard to Neriishi are

Amended claim 1 is patentable because it introduces new limitations regarding the use of chemical luminescence techniques.

In response to Applicant's arguments, please consider the following comments.

It should be appreciated that Neriishi discloses biochemical analysis unit that is used to detect the presence of analytes through by implementing selective hybridization reactions. Fluorescence is used as a means by which to detect the presence of desired biochemicals bound to probes. This is disclosed in paragraphs [0033], [0112]-[0135] and throughout the reference. The fluorescent light emitted from labeled molecules is a form of chemical luminescence.

Applicant's principle arguments in regard to the combination of Nagasawa, Maul and Beattie are

Amended claim 1 is patentable because it introduces new limitations regarding the use of chemical luminescence techniques.

In response to Applicant's arguments, please consider the following comments. It should be appreciated that Nagasawa discloses biochemical analysis unit that is used to detect the presence of analytes through by implementing selective hybridization reactions. Nagasawa's apparatus is similar to that proposed by Neriishi in that fluorescence is used as a means by which to detect the presence of desired biochemicals bound to probes. This is disclosed in paragraphs [0024]-[0030] and throughout the reference. The fluorescent light emitted from labeled molecules is a form of chemical luminescence.

Additionally, the Fernwood reference has been added to show that membrane pore sizes within the range of 1 micron to 10 microns are known in the art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NAB

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